

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ALL CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

MOTION FOR CASE MANAGEMENT ORDER

The Defendants, Ethicon, Inc., and Johnson & Johnson, move for a case management order (scheduling order) designed to manage the cases currently pending before this Court as follows:

1. As of September 10, 2013, Ethicon and Johnson & Johnson have been served with more than 17,000 complaints in this MDL and the other MDLs involving pelvic repair system products. Fewer than two-thirds of those cases have been filed with any court. Nearly 7,000 cases were served pursuant to the delayed filing agreement, entered into at the Court's urging, that tolls the statute of limitations as of the date of service of the complaint between May 2013 and October 2013, even if filing is delayed until as late as January 2014. This agreement was entered by the Court as an Agreed Order. (See PTO #49 and PTO #65). More than 600 complaints received under PTO #49 are what the Court characterized in PTO #65 as "shotgun complaints" – complaints that do not identify a specific product implanted in the plaintiff that corresponds to a named manufacturer defendant.

2. Pretrial Order #17 requires the plaintiff to serve a Plaintiff Profile Form (“PPF”) with certain information within 60 days of filing of the complaint. Through August 30, Ethicon has received approximately 6,900 PPFs. Pretrial Order #49 did not modify the timing of PPFs, so Defendants have almost no information about the nearly 10,000 Plaintiffs who have served cases under the delayed filing arrangement or who otherwise are not yet required to submit a PPF.

DISPOSITION OF FRIVOLOUS CLAIMS

3. The history of mass tort litigation teaches that a significant number of the cases likely are frivolous because, for example, they involve Plaintiffs who have no compensable injury or assert claims that are barred by the statute of limitations. Sometimes objectively frivolous claims make up the vast majority of claims in a litigation. Defendants are currently unable to determine with precision the percentage of the rapidly expanding inventory that is frivolous claims. The lack of significant information on nearly 10,000 Plaintiffs severely hampers Defendants’ ability to judge whether a spate of “implant only” and/or stale cases is driving the recent influx of claims.

4. This Court has expressed interest in the ultimate resolution of these claims, whether through litigation or settlement, and has expressed interest in procedural mechanisms to manage the litigation. Defendants believe, however, that it is impossible to develop a plan for eventual resolution without first identifying and addressing claims involving no compensable injury, claims barred by the statute of limitations, claims over which this Court has no jurisdiction or that were improperly brought in this litigation (e.g., foreign Plaintiffs), or claims barred by other defenses. *See generally* MANUAL FOR COMPLEX LITIG. (Fourth) § 22.634 (issues such as statute of limitations “may be

susceptible to resolution and review on interlocutory appeal relatively early in the litigation”). The purpose of this motion is to present procedural mechanisms for identification and prompt dismissal of meritless claims so that a realistic and fair program for resolution of the remaining cases can be developed.

5. Most of the approximately 6,900 PPFs provided to Defendants thus far are from Plaintiffs who filed the earliest claims. Historically, though anecdotally, experience tells us that the first filed cases in mass tort litigation tend to be the more serious or better cases for the Plaintiffs from the perspective of both liability and damages, and the frivolous claims tend to show up in (and sometimes drive) a massive second or third wave of filings that overwhelms the volume of initial claims. That is particularly true where, as here, pervasive lawyer advertising continues unabated throughout the litigation.

6. Pretrial Order #17 requires that each plaintiff attach to the PPF medical records available to her or her lawyer on the date of filing the complaint or PPF. In so ordering, it was contemplated that these medical records would reflect not just the identification and fact of product use, but the reason for the initial surgery and evidence that the plaintiff sustained an injury. Of the roughly 6,900 PPFs received, however, 43% (2,982) were accompanied by no medical records beyond those that establish the fact of implant (usually a few pages from an operative report). Many provided only a single sheet containing the product identification sticker. These medical records do not document any alleged injury.

7. A Plaintiff is required to have some modicum of evidence on which to base her claim before filing an action. *See, e.g., Brubaker v. City of Richmond*, 943 F.2d

1363, 1373 (4th Cir. 1991) (“Rule 11 requires that an attorney conduct a reasonable investigation of the factual and legal basis for his claim before filing. . . . A complaint containing allegations unsupported by *any* information obtained prior to filing violates the required prefiling factual investigation”) (emphasis in original); *Rojas v. Brinderson Constructors, Inc.*, 567 F. Supp. 2d 1205, 1212 (C.D. Cal. 2008) (“[I]t is plaintiffs’ duty to investigate and discover the factual bases of their claims before filing a complaint; discovery is not an open range for plaintiffs to ride roughshod in the hope that their claims may find support.”). Medical records supporting a claim for injury should be in the possession or control of the plaintiff or her lawyer before the suit is filed. Plaintiffs whose claims were filed in the absence of such records must be presumed to have no documented compensable injury. Mass tort litigation is, unfortunately, subject to abuse and pretrial investigation is essential to avoid burdening or misuse of the judicial system. *See In re Taxable Municipal Bond Securities Litigation*, Civ. A. No. MDL-863, 1994 WL 599762, at **4-5 (E.D.La. Oct. 31, 1994); *In re Welding Fume Products Liability Litigation*, No. 1:03-CV-17000, MDL No. 1535, 2006 WL 1173960, at *3 (N.D.Ohio April 5, 2006); *In re New Motor Vehicles Antitrust Litigation*, 244 F.R.D. 70, 74 (D. Me. 2007). Accordingly, Defendants will identify by December 1, 2013, those Plaintiffs who failed to present with their PPF any medical records demonstrating compensable injury and will file a motion to dismiss such claims with prejudice or, alternatively, for an order to show cause why such claims should not be dismissed with prejudice. Defendants also will seek costs and the imposition of any sanctions that the Court may deem appropriate, including those available under Rule 11. *See In Re Digitek Product Liability Litigation*, Pretrial Order # 39; *see also Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 393 (1990);

Brubaker v. City of Richmond, 943 F.2d. 1363, 1373 (4th Cir. 1991) (citing *Cleveland Demolition Co., Inc. v. Azcon Scrap Corp.*, 827 F.2d 984, 987 (4th Cir.1987)).

8. Five Plaintiffs who served a PPF in MDL 2327 did not identify in that PPF any Ethicon product allegedly responsible for her injury. As noted above, more than 650 complaints served under PTO #49 did not clearly identify the Ethicon product that allegedly caused Plaintiff's injury. These complaints do not appear to state a claim against Ethicon. *See, e.g.*, PTO #65 (shotgun complaints "almost certainly a violation of Rule 11"); *Keffer v. Wyeth*, No. 2:04-0692, 2011 U.S. Dist. LEXIS 51793 (S.D. W. Va. May 13, 2011) ("To succeed in a products liability action, a plaintiff must show that the defendant manufactured the product that injured her."); *In re Aredia and Zometa Prods. Liab. Litig.*, MDL No. 1760, No. 3:06-MD-1760, 2008 U.S. Dist. LEXIS 111836, 2008 WL 5377886 (M.D. Tenn. Dec. 2, 2008) ("Plaintiffs bear the burden of establishing the product identification information necessary to sue the correct Defendant. Plaintiffs . . . should have made that determination prior to filing suit."). By November 1, 2013, Defendants will provide a list of these Plaintiffs and file a motion to dismiss these claims or for the entry of an order to show cause why these claims should not be dismissed.

9. In addition, there are a number of duplicate filings by the plaintiffs in this litigation. We have identified over 200 plaintiffs who have served more than one case. By November 1, Defendants will provide a list of duplicate filings and ask for dismissal of duplicative filings.

10. Further review of the PPFs indicates that approximately 2,400 Plaintiffs have admitted to filing bankruptcy -- and this is to say nothing of Plaintiffs who may not have disclosed a bankruptcy filing. Experience in other mass tort litigation has shown

that (1) it is not uncommon for one to five percent to have filed bankruptcy; and (2) that an appreciable percentage of such Plaintiffs will not identify their liability claim as an asset in the bankruptcy proceeding (which extinguishes the claim under judicial estoppel). At this time, Defendants lack information about whether these Plaintiffs filed bankruptcy between the time of their implantation surgeries and filing their complaints in this litigation. By November 1, 2013, Defendants will provide the names of Plaintiffs who appear to have filed bankruptcy between the time of their implant surgery and filing their complaints and will move to dismiss those claims or, alternatively, for entry of an order to show cause why those cases should not be dismissed on the basis of judicial estoppel.

11. Complaints and PPFs received to date further show that at least 3,588 Plaintiffs with filed claims received their implants on or before December 31, 2008, and neither filed nor served a claim before January 1, 2013. Another 3,629 plaintiffs who have only served complaints pursuant to PTO #49 received their implants on or before December 31, 2008. Forty-seven states and the District of Columbia have a statute of limitations applicable to strict product liability claims of four years or less. Accordingly, these claims should be presumptively barred. Ethicon will identify these Plaintiffs by no later than January 1, 2014, and ask the Court for an order requiring those Plaintiffs to show cause why their claims should not be dismissed with prejudice as barred by the statute of limitations.

12. At this time it appears that a number of Plaintiffs are not United States citizens or residents and have improperly filed lawsuits in this proceeding. Ethicon will identify these Plaintiffs by no later than January 1, 2014, and move to dismiss such

claims or, alternatively, for entry of an order requiring those Plaintiffs to show cause why their claims should not be dismissed.

13. The schedule proposed in paragraphs 5 through 11 above should apply only to cases where a PPF was served on or before September 1, 2013. A proposed scheduling order is annexed as Exhibit "A." Defendants anticipate that at least the cases served under PTO #49 will be *filed* between now and January 2014, and PPFs should be served within sixty (60) days after filing. Accordingly, Defendants propose that a similar scheduling order be entered on April 1, 2014, applicable to cases in which abbreviated fact sheets are served after September 1, 2013.

14. Defendants do not intend that these mechanisms for addressing frivolous claims slow the MDL litigation in any way. The proposal set out below provides a mechanism for advancing the resolution of the greatest number of claims which are claims involving TVT devices.

DISPOSITION OF SUI ONLY CLAIMS

15. This litigation involves two very different types of medical devices manufactured by Ethicon. The TVT devices developed for treatment of stress urinary incontinence (SUI) remain on the market (other than TVT Secur) and today are considered the gold standard for treatment of this condition, notwithstanding this litigation. The medical devices developed for treatment of pelvic organ prolapse (Prolift, Prolift+M, and Prosima) no longer are commercially available. Accordingly, Defendants' approach to the litigation involving these two different types of medical devices is not the same.

16. The information available today indicates that more than half of the cases involve only a TVT device. Because of the wide use of these devices today, Defendants do not believe that percentage will decline; it is more likely to increase. It is also the case that due to the continued availability of these medical devices, any management mechanism the Court might implement may not stem the tide of incoming TVT cases, particularly in light of the continued mass advertising for such claims. This Court has expressed interest in some type of consolidated trial procedure to determine the issue of design defect. That proposal has deficiencies that these Defendants believe will fail to yield the results that this Court desires in terms of dealing with vast numbers of cases. *See* MANUAL FOR COMPLEX LITIG. (Fourth) § 22.93 (“Federal courts have frequently concluded that dispersed mass tort personal injury claim, particularly those involving the law of different states, cannot generally be tried on a consolidated or aggregated basis.”) Accordingly, Defendants propose an alternative approach.

17. Defendants request this Court to exercise its inherent authority under Fed. R. Civ. P. 53 and Fed. R. Evid. 706 to appoint a panel of independent experts to evaluate the *design* of the TVT devices that remain on the market. The parties will provide input on the essential areas of expertise and the specific credentials to be applied when selecting these experts, and may nominate particular experts for consideration. The Court might also seek independent recommendations for experts. After the panel of experts is proposed by the Court, the parties shall have the right to challenge the impartiality of the experts based upon conflicts or concerns of bias, but the Court, after hearing any evidence supporting and opposing the challenge, shall decide which panel members will

consider the issues. No claims of individual Plaintiffs will be considered by the expert panel.

18. The Defendants propose that each side will provide these experts with medical and scientific articles, depositions, company documents, regulatory documents, and other information the panel may deem necessary to make a determination and recommendation to the Court on the sole issue of the adequacy of the design. The experts may request additional materials they deem necessary. Defendants suggest that upon completion of the report by the expert panel and filing of appropriate motions, that an evidentiary hearing be held where the experts report and the parties present additional evidence, as necessary, and the law of all 50 states applicable to design defect can be presented to the Court. The hope is that, with the independent experts' assistance, the Court will be in a position to determine whether any properly qualified expert witness, consistent with the strictures of Rule 702 and *Daubert*, could testify that the TVT product is defectively designed under the law of any particular state (recognizing that the substantive standards for defect vary by state).

19. Because the TVT claims represent the vast majority of the claims (particularly when the combination claims are considered), Defendants believe that these claims must proceed if the litigation is to advance. Accordingly, Defendants are prepared to go forward with the currently set schedules for the January and May 2014 trial dates, but propose that the evidentiary hearing be scheduled for September 2014 in lieu of the currently scheduled Prolift trial.

Dated: September 18, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 18, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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